

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460**


Form Approved OMB No. 2070-0060

**GENERIC DATA MATRIX**

Date: 4/20/18		EPA Reg. No./File Symbol: 68506-2		Page 1 of 3	
Applicant's/Registrant's Name & Address: <b>Tessara (PTY) LTD</b> <b>c/o Delta Analytical Corp., 12510 Prosperity Drive, Suite 160, Silver Spring, MD 20904</b>		Product: Uvasys			
Ingredients: Sodium Metabisulfite (CAS No. 7681-57-4)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note

**CHEMISTRY:**

830.1550	Product identity and composition	To be assigned	Tessara (PTY) LTD	OWN	
830.1600	Description of materials used to produce the product	To be assigned	Tessara (PTY) LTD	OWN	
830.1650	Description of manufacturing process	To be assigned	Tessara (PTY) LTD	OWN	
830.1670	Discussion of formation of impurities	To be assigned	Tessara (PTY) LTD	OWN	
830.1700	Preliminary analysis	48521501	Tessara (PTY) LTD	OWN	
830.1750	Certified Limits	To be assigned	Tessara (PTY) LTD	OWN	See CSF
830.1800	Enforcement Analytical Method	47928301 43854402	Tessara (PTY) LTD	OWN	
Series 830	Part B Chemistry	N/A	N/A	PL	RED; Inorganic Sulfites, May 2007; see Note 1

Signature: 	Name & Title: Jeff Jones, Agent for Tessara (PTY) LTD	Date: 4/20/18
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**TOXICOLOGY:**

Series 870	Acute Toxicity	N/A	N/A	PL	RED Inorganic Sulfites, May 2007 and Registration Review Human Health Assessment Scoping Document, 11 Sept 2013 ; See Note 2
Series 870	Subchronic, Chronic, and Genetic Toxicity	N/A	N/A	PL	RED Inorganic Sulfites, May 2007 and Registration Review Human Health Assessment Scoping Document, 11 Sept 2013 ; See Note 2

**ECOLOGICAL EFFECTS:**

Series 850	Ecological Effects and Ecotoxicity	N/A	N/A	PL	RED; Inorganic Sulfites, May 2007 and Registration Review Preliminary Problem Formulation, 23 Jul 2013; See Note 3
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**ENVIRONMENTAL FATE:**


Series 835	Environmental Fate	N/A	N/A	PL	RED; Inorganic Sulfites, May 2007 and Registration Review Preliminary Problem Formulation, 23 Jul 2013; See Note 4
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**EXPOSURE:**

Series 875	Exposure	N/A	N/A	GAP	Non-guideline study ongoing sponsored by Sodium Metabisulfite Task Force of which Tessara is a member
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**Notes:**

- Part B requirements are addressed for technical grade sodium metabisulfite (SMBS). The final product, Uva Uno, is an impregnated pad, which serves as a delivery system for unreacted SMBS. The data cited is taken directly from the 2007 RED.
- According to May 2007 RED, "sufficient [acute] toxicity information is available for...sodium metabisulfite from publicly available sources." See attached page. The current Registration Review also considered toxicity issues and data requirements. The Human Health Assessment Scoping Document concludes that "for sulfites, the HED will consider the results of an assessment of clinical human data currently in progress at the Food and Drug Administration (FDA). Therefore, at this time the Agency is requesting no new toxicity data."
- The Registration Review Preliminary Problem Formulation stated that "[s]ince no significant sodium metabisulfite exposure is expected in the environment, ecological studies are not being requested at this time for sodium metabisulfite."
- The Registration Review Preliminary Problem Formulation stated that "[t]here are not any identified data needs for the environmental fate and transport of sodium metabisulfite and sulfur dioxide."

Signature: 	Name & Title: Jeff Jones, Agent for Tessara (PTY) LTD	Date: 4/20/18
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